IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S and LEO PHARMA INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
GLENMARK PHARMACEUTICALS LTD.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs LEO Pharma A/S and LEO Pharma, Inc. (collectively, "LEO" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Glenmark Pharmaceuticals Ltd. ("Glenmark" or "Defendant"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 214688 (hereinafter, "Glenmark's ANDA"), filed by and for the benefit of Glenmark with the United States Food and Drug Administration ("FDA"). Through Glenmark's ANDA, Glenmark seeks approval to market a generic version ("Glenmark's ANDA Product") of LEO's innovative ENSTILAR® pharmaceutical product, a foam containing calcipotriene and betamethasone dipropionate as active pharmaceutical ingredients at dosage strengths of 0.005% and 0.064%, respectively, prior to the expiration of LEO's United States Patent Nos. 10,617,698 ("the '698 Patent"), 10,660,908 ("the '908 Patent"), 10,682,364 ("the '364 Patent"), 10,688,108 ("the '108 Patent"), and 10,716,799 ("the '799 Patent") (collectively, "the Patents-in-Suit").

THE PARTIES

2. Plaintiff LEO Pharma A/S is a company organized and existing under the laws of Denmark with its headquarters at Industriparken 55, DK-2750 Ballerup, Denmark. LEO Pharma A/S is a research-based company dedicated to developing innovative drugs to help patients with dermatologic conditions.

3. Plaintiff LEO Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 7 Giralda Farms, Madison, NJ 07940. LEO Pharma, Inc. is a wholly owned subsidiary of LEO Pharma A/S.

4. On information and belief, Defendant Glenmark Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a registered office at B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400026, India and a corporate office at Glenmark House, B.D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (East), Mumbai 400099, India.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271, for infringement of the Patents-in-Suit.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Defendant Glenmark because, *inter alia*, on information and belief, Glenmark has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Glenmark's ANDA Product in the State of Delaware upon approval of ANDA No. 214688.

8. On information and belief, Glenmark also controls and directs a wholly owned subsidiary in the United States named Glenmark Therapeutics Inc., USA, which is a Delaware corporation and has a place of business at 750 Corporate Dr., Mahwah, New Jersey 07430.

9. On information and belief, Glenmark is in the business of making, obtaining regulatory approval for, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and subsidiaries, from which Glenmark derives a substantial portion of its revenue.

10. On information and belief, Glenmark, through its own actions and through the actions of its agents and subsidiaries, engaged in the preparation and filing of ANDA No. 214688, continues to engage in seeking FDA approval of ANDA No. 214688, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Glenmark's ANDA Product throughout the United States, including within the State of Delaware, and stands to benefit if FDA approves ANDA No. 214688.

11. On information and belief, Glenmark, through its own actions and through the actions of its agents and subsidiaries, prepared and submitted ANDA No. 214688 with a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

12. On information and belief, if FDA approves ANDA No. 214688, Glenmark intends to market, offer to sell, sell, or distribute Glenmark's ANDA Product throughout the United States and within the State of Delaware, that will, as explained below, infringe upon LEO's rights in the Patents-in-Suit protecting its ENSTILAR® product. On information and belief, if FDA approves ANDA No. 214688, Glenmark knows and intends that Glenmark's ANDA Product will be used, distributed, offered for sale, and sold in the United States and within the State of Delaware.

13. This Court also has personal jurisdiction over Glenmark at least because, *inter alia*, (a) Glenmark has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product in the United States, including in the State of Delaware; (b) Glenmark, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Glenmark's ANDA Product in the United States, including in the State of Delaware and to residents of this Judicial District, upon approval of ANDA No. 214688, and will derive substantial revenue from the use of Glenmark's ANDA Product in the State of Delaware; and (c) Glenmark has purposefully availed itself of the privilege of doing business in the State of Delaware by placing goods into the stream of commerce for distribution throughout the United States and within the State of Delaware, and/or by selling, directly or through its agents, pharmaceutical products in the State of Delaware. On information and belief, if ANDA No. 214688 is approved, Glenmark's ANDA Product charged with infringing the Patents-in-Suit would, *inter alia*, be distributed, offered for sale, and sold in the State of Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware, all of which would have a substantial effect on Delaware.

14. This Court also has personal jurisdiction over Glenmark because Glenmark has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to LEO, which manufactures the ENSTILAR® drug product for sale and use throughout the United States, including in this Judicial District. On information and belief, Glenmark filed ANDA No. 214688 with a Paragraph IV Certification, which was purposefully directed to the State of Delaware, where LEO Pharma, Inc. is organized. As a result, the consequences of Glenmark's actions were, and will be, suffered in

the State of Delaware. Glenmark knew or should have known that the consequences of its actions were, and will be, suffered in the State of Delaware. At the time Glenmark sent notice of the Paragraph IV Certification, it was reasonably foreseeable that Glenmark would be sued within 45 days in this Judicial District, where LEO Pharma, Inc. is organized. On information and belief, Glenmark's actions, if not enjoined, will injure LEO by displacing at least some of LEO's sales of ENSTILAR® in this Judicial District, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of ENSTILAR® in this Judicial District.

15. In the alternative, this Court has personal jurisdiction over Glenmark because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) LEO's claims arise under federal law; (b) Glenmark is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Glenmark has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Glenmark satisfies due process.

16. On information and belief, Glenmark has also engaged in substantial, systematic, and continuous contacts with Delaware that satisfy due process and confer personal jurisdiction over Glenmark in Delaware.

17. On information and belief, Glenmark is a foreign corporation, and venue is proper in this Judicial District pursuant to at least 28 U.S.C. § 1391(c)(3).

18. Glenmark has consented to personal jurisdiction and venue in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Astellas US LLC et al. v. Glenmark Pharms. Ltd.*, Civil Action No. 1:20-cv-516 (CVC) (D. Del) (D.I. 10, June 8, 2020); *Novartis Pharms. Corp. v. Apotex Inc. et al.*, Civil Action No.

1:20-cv-133 (LPS) (D. Del.) (D.I. 11, Feb. 18, 2020); *Pfizer Inc. et al. v. Glenmark Pharms. Ltd. et al.*, Civil Action No. 1:19-cv-1209 (RGA) (D. Del.) (D.I. 15, Sept. 3, 2019). Glenmark has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

LEO'S PATENTS AND INNOVATIVE ENSTILAR® DRUG PRODUCT

19. LEO Pharma is the holder of New Drug Application ("NDA") No. 207589 for calcipotriene/betamethasone diproprionate foam, 0.005% and 0.064%, which was approved by the FDA on October 16, 2015. LEO markets this innovative drug product under the trade name ENSTILAR®.

20. LEO's ENSTILAR® product is approved for the topical treatment of plaque psoriasis. A true and correct copy of prescribing information for LEO's ENSTILAR® product is attached as Exhibit A.

21. ENSTILAR® and one or more of its approved uses are covered by claims of the Patents-in-Suit.

22. The Patents-in-Suit are listed in *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "*Orange Book*") in connection with NDA No. 207589.

23. LEO Pharma A/S, as the assignee, owns the entire right, title, and interest in each of the Patents-in-Suit. LEO Pharma, Inc. is the exclusive licensee of the Patents-in-Suit. LEO has the right to enforce each of these Patents.

24. The '698 Patent is entitled, "Pharmaceutical Spray Composition Comprising a Vitamind D Analogue and a Corticosteroid." The '698 Patent was duly and legally issued on April

14, 2020. The *Orange Book* states that the '698 Patent's term ends on June 10, 2031. A true and correct copy of the '698 Patent is attached as Exhibit B.

25. The '908 Patent is entitled, "Pharmaceutical Spray Composition Comprising a Vitamin D Analogue and a Corticosteroid." The '908 Patent was duly and legally issued on May 26, 2020. The *Orange Book* states that the '908 Patent's term ends on June 10, 2031. A true and correct copy of the '908 Patent is attached as Exhibit C.

26. The '364 Patent is entitled, "Pharmaceutical Spray Composition Comprising a Vitamind D Analogue and a Corticosteroid." The '364 Patent was duly and legally issued on June 16, 2020. The *Orange Book* states that the '364 Patent's term ends on June 10, 2031. A true and correct copy of the '364 Patent is attached as Exhibit D.

27. The '108 Patent is entitled, "Pharmaceutical Spray Composition Comprising a Vitamin D Analogue and a Corticosteroid." The '108 Patent was duly and legally issued on June 23, 2020. The *Orange Book* states that the '108 Patent's term ends on June 10, 2031. A true and correct copy of the '108 Patent is attached as Exhibit E.

28. The '799 Patent is entitled, "Pharmaceutical Spray Composition Comprising a Vitamin D Analogue and a Corticosteroid." The '799 Patent was duly and legally issued on July 21, 2020. The *Orange Book* states that the '799 Patent's term ends on June 10, 2031. A true and correct copy of the '799 Patent is attached as Exhibit F.

GLENMARK'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

29. On information and belief, Glenmark has submitted or caused to be submitted to FDA ANDA No. 214688 under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the calcipotriene/betamethasone dipropionate foam described therein, as a purported generic version of ENSTILAR®, prior to the expiration of the Patents-in-Suit.

30. On information and belief, FDA has not yet approved ANDA No. 214688.

31. On August 25, 2020, LEO received a Notice of Paragraph IV Certification from Glenmark dated August 24, 2020 ("Notice Letter"). The Notice Letter represented that Glenmark had submitted to FDA ANDA No. 214688 with a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the products described in ANDA No. 214688 before the expiration of the patents listed in the *Orange Book* for ENSTILAR®. Hence, Glenmark's purpose in submitting ANDA No. 214688 is to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Glenmark's ANDA Product before the expiration of the Patents-in-Suit.

32. The Notice Letter states that the Paragraph IV Certification in ANDA No. 214688 alleges that the Patents-in-Suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Glenmark's ANDA Product.

33. The Notice Letter contained a purported detailed statement of the factual and legal basis for Glenmark's allegation that the Patents-in-Suit are purportedly invalid, unenforceable, or not infringed by the manufacture, use, offer for sale, sale, or importation into the United States of Glenmark's ANDA Product.

34. On information and belief, Glenmark, through its own actions and through the actions of its agents and subsidiaries, has assisted with and participated in the preparation and submission of ANDA No. 214688, has provided material support to the preparation and submission of ANDA No. 214688, and intends to support the further prosecution of ANDA No. 214688.

35. On information and belief, if FDA approves ANDA No. 214688, Glenmark will manufacture, offer to sell, or sell Glenmark's ANDA Product within the United States, including within the State of Delaware, or will import Glenmark's ANDA Product into the United States, including Delaware.

36. On information and belief, if FDA approves ANDA No. 214688, Glenmark will actively induce or contribute to the manufacture, use, offer to sell, sale, or importation of Glenmark's ANDA Product in the United States.

37. LEO brings this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of the Notice Letter.

COUNT 1
INFRINGEMENT OF THE '698 PATENT

38. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

39. Glenmark has submitted or caused the submission of ANDA No. 214688 to the FDA, and continues to seek FDA approval of ANDA No. 214688.

40. Glenmark has infringed at least claim 1 of the '698 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214688 and seeking FDA approval of ANDA No. 214688 prior to the expiration of the '698 Patent.

41. The '698 Patent includes claims, such as at least claim 1, that recite, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and said composition results in increased skin permeation of calcipotriol.

42. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claim 1 of the '698 Patent. *See supra* ¶ 41.

43. Glenmark's commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's ANDA Product would directly infringe, and would actively induce or contribute to infringement of, at least claim 1 of the '698 Patent. Upon information and belief, upon FDA approval of ANDA No. 214688, Glenmark will market and distribute Glenmark's ANDA Product to third parties including resellers, pharmacies, hospitals and other clinics. Unless enjoined by this Court, upon FDA approval of ANDA No. 214688, Glenmark will make, use, offer to sell, or sell Glenmark's ANDA Product within the United States, or will import Glenmark's ANDA Product into the United States, and will thereby infringe, induce the infringement of, and contribute to the infringement of at least claim 1 of the '698 Patent.

44. On information and belief, upon FDA approval of ANDA No. 214688, Glenmark, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Glenmark's ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Glenmark's ANDA Product. On information and belief, Glenmark will knowingly and intentionally include with Glenmark's ANDA Product a product label and product insert that will include instructions for using or administering Glenmark's ANDA Product. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claim 1 of the '698 Patent. Glenmark will

induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Glenmark's ANDA Product to directly infringe at least claim 1 of the '698 Patent. On information and belief, Glenmark will encourage acts of direct infringement with knowledge of the '698 Patent and knowledge that it is encouraging infringement.

45. Glenmark had actual and constructive notice of the '698 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '698 Patent would constitute an act of infringement of the '698 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '698 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '698 Patent.

46. LEO will be irreparably harmed if Glenmark is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the '698 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Glenmark, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 2
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '698 PATENT

47. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

48. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. The ’698 Patent includes claims, such as at least claim 1, that recite, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and said composition results in increased skin permeation of calcipotriol.

50. On information and belief, Glenmark’s ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claim 1 of the ’698 Patent. *See supra* ¶ 49.

51. On information and belief, if Glenmark’s ANDA is approved, Glenmark’s ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, or will be imported into the United States, including the State of Delaware, by or through Glenmark and its affiliates. Glenmark will therefore directly infringe at least claim 1 of the ’698 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

52. On information and belief, Glenmark knows that healthcare professionals or patients will use Glenmark’s ANDA Product in accordance with the labeling sought in Glenmark’s ANDA. On information and belief, the product label and product insert accompanying Glenmark’s ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claim 1 of the ’698 Patent. Glenmark will therefore contribute to, or induce, the infringement of one or more claims of the ’698 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

53. On information and belief, Glenmark's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product complained of herein, will begin immediately after the FDA approves Glenmark's ANDA. Any such conduct before the '698 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of at least claim 1 of the '698 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

54. Glenmark had actual and constructive notice of the '698 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '698 Patent would constitute an act of infringement of the '698 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '698 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '698 Patent.

55. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Glenmark concerning liability for the infringement of the '698 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

56. LEO will be substantially and irreparably harmed by Glenmark's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

57. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 3
INFRINGEMENT OF THE '908 PATENT

58. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

59. Glenmark has submitted or caused the submission of ANDA No. 214688 to the FDA, and continues to seek FDA approval of ANDA No. 214688.

60. Glenmark has infringed at least claims 1 and 14 of the '908 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214688 and seeking FDA approval of ANDA No. 214688 prior to the expiration of the '908 Patent.

61. The '908 Patent includes claims, such as at least claims 1 and 14, that recite, *inter alia*, a topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, a propellant, and a lipid carrier, wherein the formulation does not include propylene glycol, the calcipotriol or calcipotriol monohydrate and betamethasone dipropionate are dissolved in the propellant, and a semi-solid and occlusive layer forms after application.

62. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claims 1 and 14 of the '908 Patent. *See supra* ¶ 61.

63. Glenmark's commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's ANDA Product would directly infringe, and would actively induce or contribute to infringement of, at least claims 1 and 14 of the '908 Patent. Upon information and belief, upon FDA approval of ANDA No. 214688, Glenmark will market and distribute Glenmark's ANDA Product to third parties including resellers, pharmacies, hospitals and other clinics. Unless enjoined by this Court, upon FDA approval of ANDA No. 214688,

Glenmark will make, use, offer to sell, or sell Glenmark's ANDA Product within the United States, or will import Glenmark's ANDA Product into the United States, and will thereby infringe, induce the infringement of, and contribute to the infringement of at least claims 1 and 14 of the '908 Patent.

64. On information and belief, upon FDA approval of ANDA No. 214688, Glenmark, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Glenmark's ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Glenmark's ANDA Product. On information and belief, Glenmark will knowingly and intentionally include with Glenmark's ANDA Product a product label and product insert that will include instructions for using or administering Glenmark's ANDA Product. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claims 1 and 14 of the '908 Patent. Glenmark will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Glenmark's ANDA Product to directly infringe at least claims 1 and 14 of the '908 Patent. On information and belief, Glenmark will encourage acts of direct infringement with knowledge of the '908 Patent and knowledge that it is encouraging infringement.

65. Glenmark had actual and constructive notice of the '908 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '908 Patent would constitute an act of infringement of the '908 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the

'908 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '908 Patent.

66. LEO will be irreparably harmed if Glenmark is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the '908 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Glenmark, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 4
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '908 PATENT

67. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

68. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

69. The '908 Patent includes claims, such as at least claims 1 and 14, that recite, *inter alia*, a topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, a propellant, and a lipid carrier, wherein the formulation does not include propylene glycol, the calcipotriol or calcipotriol monohydrate and betamethasone dipropionate are dissolved in the propellant, and a semi-solid and occlusive layer forms after application.

70. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claims 1 and 14 of the '908 Patent. *See supra* ¶ 69.

71. On information and belief, if Glenmark's ANDA is approved, Glenmark's ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, or will be imported into the United States, including the State of Delaware, by or through Glenmark and its affiliates. Glenmark will therefore directly infringe at least claims 1 and 14 of the '908 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

72. On information and belief, Glenmark knows that healthcare professionals or patients will use Glenmark's ANDA Product in accordance with the labeling sought in Glenmark's ANDA. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claims 1 and 14 of the '908 Patent. Glenmark will therefore contribute to, or induce, the infringement of one or more claims of the '908 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

73. On information and belief, Glenmark's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product complained of herein, will begin immediately after the FDA approves Glenmark's ANDA. Any such conduct before the '908 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of at least claims 1 and 14 of the '908 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

74. Glenmark had actual and constructive notice of the '908 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '908 Patent would constitute an act of infringement of the

'908 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '908 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '908 Patent.

75. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Glenmark concerning liability for the infringement of the '908 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

76. LEO will be substantially and irreparably harmed by Glenmark's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

77. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 5
INFRINGEMENT OF THE '364 PATENT

78. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

79. Glenmark has submitted or caused the submission of ANDA No. 214688 to the FDA, and continues to seek FDA approval of ANDA No. 214688.

80. Glenmark has infringed at least claim 1 of the '364 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214688 and seeking FDA approval of ANDA No. 214688 prior to the expiration of the '364 Patent.

81. The ’364 Patent includes claims, such as at least claim 1, that recite, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and the calcipotriol or calcipotriol monohydrate has degraded no more than a specific amount under certain conditions.

82. On information and belief, Glenmark’s ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claim 1 of the ’364 Patent. *See supra* ¶ 81.

83. Glenmark’s commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark’s ANDA Product would directly infringe, and would actively induce or contribute to infringement of, at least claim 1 of the ’364 Patent. Upon information and belief, upon FDA approval of ANDA No. 214688, Glenmark will market and distribute Glenmark’s ANDA Product to third parties including resellers, pharmacies, hospitals and other clinics. Unless enjoined by this Court, upon FDA approval of ANDA No. 214688, Glenmark will make, use, offer to sell, or sell Glenmark’s ANDA Product within the United States, or will import Glenmark’s ANDA Product into the United States, and will thereby infringe, induce the infringement of, and contribute to the infringement of at least claim 1 of the ’364 Patent.

84. On information and belief, upon FDA approval of ANDA No. 214688, Glenmark, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Glenmark’s ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Glenmark’s ANDA Product. On information and belief, Glenmark will knowingly and intentionally include with Glenmark’s ANDA Product a product

label and product insert that will include instructions for using or administering Glenmark's ANDA Product. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claim 1 of the '364 Patent. Glenmark will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Glenmark's ANDA Product to directly infringe at least claim 1 of the '364 Patent. On information and belief, Glenmark will encourage acts of direct infringement with knowledge of the '364 Patent and knowledge that it is encouraging infringement.

85. Glenmark had actual and constructive notice of the '364 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '364 Patent would constitute an act of infringement of the '364 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '364 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '364 Patent.

86. LEO will be irreparably harmed if Glenmark is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the '364 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Glenmark, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 6
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '364 PATENT

87. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

88. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

89. The '364 Patent includes claims, such as at least claim 1, that recite, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and the calcipotriol or calcipotriol monohydrate has degraded no more than a specific amount under certain conditions.

90. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claim 1 of the '364 Patent. *See supra* ¶ 89.

91. On information and belief, if Glenmark's ANDA is approved, Glenmark's ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, or will be imported into the United States, including the State of Delaware, by or through Glenmark and its affiliates. Glenmark will therefore directly infringe at least claim 1 of the '364 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

92. On information and belief, Glenmark knows that healthcare professionals or patients will use Glenmark's ANDA Product in accordance with the labeling sought in Glenmark's ANDA. On information and belief, the product label and product insert accompanying Glenmark's

ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claim 1 of the '364 Patent. Glenmark will therefore contribute to, or induce, the infringement of one or more claims of the '364 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

93. On information and belief, Glenmark's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product complained of herein, will begin immediately after the FDA approves Glenmark's ANDA. Any such conduct before the '364 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of at least claim 1 of the '364 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

94. Glenmark had actual and constructive notice of the '364 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '364 Patent would constitute an act of infringement of the '364 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '364 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '364 Patent.

95. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Glenmark concerning liability for the infringement of

the ’364 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

96. LEO will be substantially and irreparably harmed by Glenmark’s infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

97. This case is exceptional, and LEO is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 7
INFRINGEMENT OF THE ’108 PATENT

98. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

99. Glenmark has submitted or caused the submission of ANDA No. 214688 to the FDA, and continues to seek FDA approval of ANDA No. 214688.

100. Glenmark has infringed at least claims 1, 8, and 13 of the ’108 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214688 and seeking FDA approval of ANDA No. 214688 prior to the expiration of the ’108 Patent.

101. The ’108 Patent includes claims, such as at least claims 1, 8, and 13, that recite, *inter alia*, a method of treating psoriasis comprising administering a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and certain other conditions are met.

102. On information and belief, Glenmark’s ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate and Glenmark’s ANDA includes prescribing information instructions meeting all elements of at least claims 1, 8, and 13 of the ’108 Patent. *See supra* ¶ 101.

103. Glenmark's commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's ANDA Product would directly infringe, and would actively induce or contribute to infringement of, at least claims 1, 8, and 13 of the '108 Patent. Upon information and belief, upon FDA approval of ANDA No. 214688, Glenmark will market and distribute Glenmark's ANDA Product to third parties including resellers, pharmacies, hospitals and other clinics. Unless enjoined by this Court, upon FDA approval of ANDA No. 214688, Glenmark will make, use, offer to sell, or sell Glenmark's ANDA Product within the United States, or will import Glenmark's ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of at least claims 1, 8, and 13 of the '108 Patent.

104. On information and belief, upon FDA approval of ANDA No. 214688, Glenmark, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Glenmark's ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Glenmark's ANDA Product. On information and belief, Glenmark will knowingly and intentionally include with Glenmark's ANDA Product a product label and product insert that will include instructions for using or administering Glenmark's ANDA Product. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claims 1, 8, and 13 of the '108 Patent. Glenmark will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Glenmark's ANDA Product to directly infringe at least claims 1, 8, and 13 of the '108

Patent. On information and belief, Glenmark will encourage acts of direct infringement with knowledge of the '108 Patent and knowledge that it is encouraging infringement.

105. Glenmark had actual and constructive notice of the '108 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '108 Patent would constitute an act of infringement of the '108 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '108 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '108 Patent.

106. LEO will be irreparably harmed if Glenmark is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the '108 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Glenmark, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 8
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '108 PATENT

107. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

108. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

109. The '108 Patent includes claims, such as at least claims 1, 8, and 13, that recite, *inter alia*, methods of treating psoriasis comprising administering a sprayable topical composition

comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and certain other conditions are met.

110. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate and Glenmark's ANDA includes prescribing information instructions meeting all elements of at least claims 1, 8, and 13 of the '108 Patent. *See supra* ¶ 109.

111. On information and belief, if Glenmark's ANDA is approved, Glenmark's ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, or will be imported into the United States, including the State of Delaware, by or through Glenmark and its affiliates. Glenmark will therefore directly infringe at least claims 1, 8, and 13 of the '108 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

112. On information and belief, Glenmark knows that healthcare professionals or patients will use Glenmark's ANDA Product in accordance with the labeling sought in Glenmark's ANDA. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claims 1, 8, and 13 of the '108 Patent. Glenmark will therefore contribute to, or induce, the infringement of one or more claims of the '108 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

113. On information and belief, Glenmark's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product

complained of herein, will begin immediately after the FDA approves Glenmark's ANDA. Any such conduct before the '108 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of at least claims 1, 8, and 13 of the '108 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

114. Glenmark had actual and constructive notice of the '108 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '108 Patent would constitute an act of infringement of the '108 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '108 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '108 Patent.

115. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Glenmark concerning liability for the infringement of the '108 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

116. LEO will be substantially and irreparably harmed by Glenmark's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

117. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 9
INFRINGEMENT OF THE '799 PATENT

118. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

119. Glenmark has submitted or caused the submission of ANDA No. 214688 to the FDA, and continues to seek FDA approval of ANDA No. 214688.

120. Glenmark has infringed at least claim 1 of the '799 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214688 and seeking FDA approval of ANDA No. 214688 prior to the expiration of the '799 Patent.

121. The '799 Patent includes claims, such as at least claim 1, that recite, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and has no observed visible crystals of calcipotriol, calcipotriol monohydrate, or betamethasone dipropionate under specified conditions.

122. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claim 1 of the '799 Patent. *See supra* ¶ 121.

123. Glenmark's commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's ANDA Product would directly infringe, and would actively induce or contribute to infringement of, at least claim 1 of the '799 Patent. Upon information and belief, upon FDA approval of ANDA No. 214688, Glenmark will market and distribute Glenmark's ANDA Product to third parties including resellers, pharmacies, hospitals and other clinics. Unless enjoined by this Court, upon FDA approval of ANDA No. 214688, Glenmark will

make, use, offer to sell, or sell Glenmark's ANDA Product within the United States, or will import Glenmark's ANDA Product into the United States, and will thereby infringe, induce the infringement of, and contribute to the infringement of at least claim 1 of the '799 Patent.

124. On information and belief, upon FDA approval of ANDA No. 214688, Glenmark, through its own actions and through the actions of its agents and subsidiaries, will market and distribute Glenmark's ANDA Product to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Glenmark's ANDA Product. On information and belief, Glenmark will knowingly and intentionally include with Glenmark's ANDA Product a product label and product insert that will include instructions for using or administering Glenmark's ANDA Product. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claim 1 of the '799 Patent. Glenmark will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Glenmark's ANDA Product to directly infringe at least claim 1 of the '799 Patent. On information and belief, Glenmark will encourage acts of direct infringement with knowledge of the '799 Patent and knowledge that it is encouraging infringement.

125. Glenmark had actual and constructive notice of the '799 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '799 Patent would constitute an act of infringement of the '799 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '799 Patent, and is not a staple article or commodity of commerce suitable for substantial non-

infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '799 Patent.

126. LEO will be irreparably harmed if Glenmark is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the '799 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Glenmark, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 10
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '799 PATENT

127. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

128. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

129. The '799 Patent includes claims, such as at least claim 1, that recite, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate, betamethasone dipropionate, an antioxidant, and a propellant and lipid carrier in specified amounts, wherein the formulation does not include propylene glycol and has no observed visible crystals of calcipotriol, calcipotriol monohydrate, or betamethasone dipropionate under specified conditions.

130. On information and belief, Glenmark's ANDA Product contains, *inter alia*, a sprayable topical composition comprising calcipotriol or calcipotriol monohydrate and betamethasone dipropionate that meets all elements of at least claim 1 of the '799 Patent. *See supra* ¶ 129.

131. On information and belief, if Glenmark's ANDA is approved, Glenmark's ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, or will be imported into the United States, including the State of Delaware, by or through Glenmark and its affiliates. Glenmark will therefore directly infringe at least claim 1 of the '799 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

132. On information and belief, Glenmark knows that healthcare professionals or patients will use Glenmark's ANDA Product in accordance with the labeling sought in Glenmark's ANDA. On information and belief, the product label and product insert accompanying Glenmark's ANDA Product will include instructions that are substantially similar to the instructions found in the prescribing information for ENSTILAR®, attached as Exhibit A, and which, if followed, will cause infringement of at least claim 1 of the '799 Patent. Glenmark will therefore contribute to, or induce, the infringement of one or more claims of the '799 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

133. On information and belief, Glenmark's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product complained of herein, will begin immediately after the FDA approves Glenmark's ANDA. Any such conduct before the '799 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement of at least claim 1 of the '799 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

134. Glenmark had actual and constructive notice of the '799 Patent prior to filing Glenmark's ANDA and was aware that the filing of Glenmark's ANDA with the request for FDA approval prior to the expiration of the '799 Patent would constitute an act of infringement of the

'799 Patent. Glenmark will offer to sell, sell, and/or import into the United States Glenmark's ANDA Product with knowledge that the same is especially made for use in an infringement of the '799 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing uses. Glenmark had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product would not contribute to, or induce, the infringement of the '799 Patent.

135. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Glenmark concerning liability for the infringement of the '799 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

136. LEO will be substantially and irreparably harmed by Glenmark's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

137. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, LEO respectfully requests the following relief:

(a) The entry of a judgment, in favor of LEO and against Glenmark, that Glenmark's submission of ANDA No. 214688 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Glenmark's ANDA Product before the expiration of the Patents-in-Suit was an act of infringement of one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A);

(b) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 214688 shall be a date that is not earlier than the last of the

expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which LEO is or becomes entitled;

(c) The entry of a declaratory judgment, in favor of LEO and against Glenmark, declaring that Glenmark's commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, Glenmark's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the Patents-in-Suit by Glenmark under one or more of 35 U.S.C. § 271(a), (b), and (c);

(d) The entry of preliminary and permanent injunctions enjoining Glenmark and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Glenmark, and their successors or assigns, from commercially manufacturing, using, offering to sell, or selling Glenmark's ANDA Product within the United States, or importing Glenmark's ANDA Product into the United States, or inducing or contributing to such conduct, until the last of the expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which LEO is or becomes entitled;

(e) The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Glenmark and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Glenmark, and their successors or assigns, from commercially manufacturing, using, offering to sell, or selling Glenmark's ANDA Product within the United States, or importing Glenmark's ANDA Product into the United States, or inducing or contributing to such conduct, until the last of the expiration dates of the Patents-in-Suit, including any

extensions or regulatory exclusivities, or any later expiration of exclusivity to which LEO is or becomes entitled;

(f) A declaration under 28 U.S.C. § 2201 that if Glenmark, its officers, directors, agents, servants, employees, representatives, attorneys, parents, subsidiaries, affiliates, other related business entities, or other persons or entities acting or attempting to act in concert, participation, or in privity with Glenmark, or acting on Glenmark's behalf, engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, Glenmark's ANDA Product, then it will constitute an act of direct or indirect infringement of the Patents-in-Suit;

(g) The entry of a judgment declaring that the Patents-in-Suit remain valid and enforceable;

(h) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Glenmark engages in the commercial manufacture, use, offer for sale, sale, or importation of Glenmark's ANDA Product, or any product that infringes the Patents-in-Suit, or induces or contributes to such conduct, prior to the expiration of such patents, including any extensions or regulatory exclusivities;

(i) The entry of judgment declaring that Glenmark's acts render this case an exceptional case and awarding LEO its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(j) An award to LEO of its costs and expenses in this action; and

(k) Such other and further relief this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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